510(K) Summary, K11

K110856

AUG 10 2011

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Date prepared: March 18, 2011
Contact person: Vincenzo Velardi, President and CEO

1. **Identification of the Device:**
   Proprietary-Trade Name: R104/A, R108 and R108 F Manual X-Ray Collimators
   Classification Name: collimator, automatic, radiographic, Product Code IZX
   Common/Usual Name: Manual X-Ray Collimator.

2. **Equivalent legally marketed devices**: K030487 Ralco R72 Manual Collimator.

3. **Indications for Use** (intended use): Intended for use in diagnostic/fluoroscopic applications.

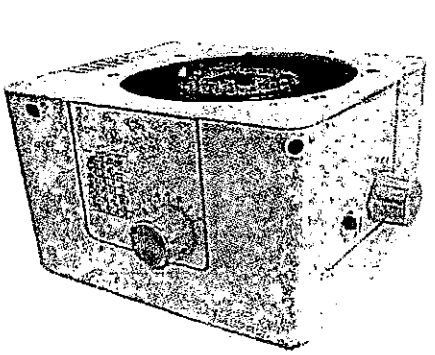
4. **Description of the Device**: These are square-field single- or, optionally, multi-layer x-ray collimators. They are lightweight and compact, suited for installation on mobile or fixed x-ray equipment. In the standard single- layer version, the x-ray field is defined by two pairs of shutters and a cone at the xray beam window. In the version mounting RO 334, he x-ray field is defined by six pairs of shutters, two of which are leadlined. The six pairs of shutters move perpendicularly within the x-ray field. Four pairs of shutters are in bronze: two are located near the focus and two are located near the entrance window. Two leaded shutters are located near the exit window of the x-ray beam from the collimator and serve to accurately define the x-ray field edges. Shutter movements are manual and controlled by two knobs on the collimator front panel. The square-field X-ray beam Limiting Device is designed for installation on rotating or fixed anode Xray tubes (mounting RO 334) (EN 60601-1-3 par 29.202.3); manual controls provide for the adjustment of the X-ray field dimension to the size of the image receptor or to that of the anatomical area of interest. Adjustment to the area under investigation is possible by using the knobs on the front panel. Direct visualisation of the x-ray field is provided by a light beam which corresponds to the x-ray beam, within a tolerance of two percent of the selected FFD (SID) value. The light-field centre is provided by the intersection of two perpendicular lines silk-screened into the Lexan window and projected on the light field by the light beam. To activate the light field, press the area marked with the light symbol on the front of the device. The light will switch on for 30 seconds and an electronic timer will switch the lamp OFF automatically.

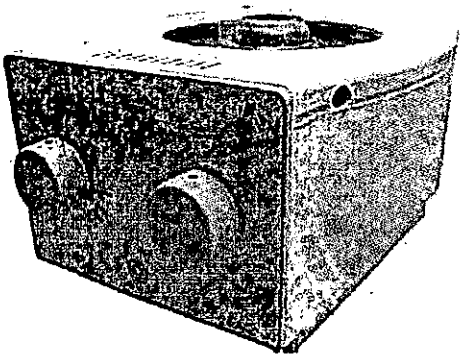
5. **Safety and Effectiveness,** comparison to predicate device. The results of bench, safety test, and laboratory testing indicates that the new devices are as safe and effective as the predicate device. The predicate employs a square field, same as our new device. The new devices conform to US Performance Standards and are CSA Listed to US Standards for safety for medical devices.

6. **Conclusion:** After analyzing both bench and safety testing data, it is the conclusion of Ralco that the R104/A, R108 and R108 F Manual X-Ray Collimators are as safe and effective as the predicate device, have few technological differences, and has identical indications for use, thus rendering them substantially equivalent to the predicate device.

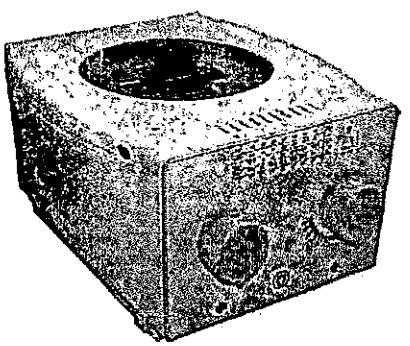
7. **Comparison Photographs:**

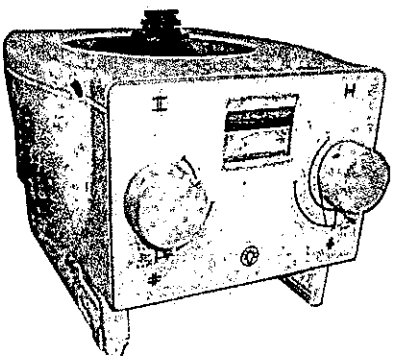
Predicate **R104/A**





R108 **R108 F**





DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

RALCO S.R.L.
% Mr. Daniel Kamm, P.E.
Regulatory Engineer
Kamm & Associates
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AUG 10 2011

Re: K110856
Trade/Device Name: R104/A, R108 and R108 F Manual X-Ray Collimators
Regulation Number: 21 CFR 892.1610
Regulation Name: Diagnostic x-ray beam limiting device
Regulatory Class: II
Product Code: IZX
Dated: August 7, 2011
Received: August 8, 2011

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110856

Device Name: R104/A, R108 and R108 F Manual X-Ray Collimators

Indications For Use:

R104/A, R108 and R108 F Manual X-Ray Collimators are intended for use in diagnostic radiographic/fluoroscopic applications.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110856